K020630

510(k) Summary for the Ultrasonix Ergosonix 500 Ultrasound Scanner

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Devices Act of 1990 revisions to 21 CFR, Part 807.92, Content and format of a 510(k) Summary.

1.0 Submitter Information

JUN 1 3 2002

1.1 Submitter:

Ultrasonix Medical Corporation
535 – 2660 Oak Street
Vancouver, British Columbia
Canada. V6H 3Z1

1.2 Contact:

Ken Seto
Quality Assurance / Regulatory Engineer
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(604) 875 – 4985

Other Contact:

Laurent Pelissier
Chief Technical Officer
laurent@ultrasonix.com
(604) 875 – 5295

1.3 Date prepared:

February 20 2002

2.0 Device Name

2.1 Common Name:

Ultrasound Imaging System

2.2 Proprietary name:

Ultrasonix Ergosonix 500 Ultrasound Scanner

2.3 Classification Name:

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892-1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

2.4 Classification:

Class II

2.5 Predicate Device:

ATL HDI 5000 System (K002003)
Acuson Sequoia (K973767)

2.6 Reason for submission:

New product

3.0 Device Description

The Ultrasonix Ergosonix 500 Ultrasound Diagnostic Scanner is highly mobile, software-controlled, diagnostic ultrasound system capable of the following operating modes: 2D B-mode, M, Pulsed Doppler, Color Flow (including amplitude Doppler). The system can generate real-time compound images and harmonic images.

The system is designed for use in linear and convex scanning modes, and supports linear, convex, and microconvex probes.

Frequency Range	2-15MHz
Transducer types	Linear array Curved array Intracavitary array

The Ultrasonix Ergosonix 500 is designed to comply to the following standards:

- **EN 60601-1**: European Norm, Medical Electrical Equipment
- **UL 2601-1**: Underwriters Laboratories Standards, Medical Electrical Equipment

- **C22-2 No 601-1**, Canadian Standards Association, Medical Electrical Equipment
- **EN 60601-1-2** : European Norm, Collateral Standard, Electromagnetic Compatibility
- **IEC 60601-2-37**: Particular requirements for the safety of ultrasonic medical diagnostic equipment
- AIUM "Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment" Jan 1998
- AIUM "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices"

4.0 Summary of Intended Uses

The Ultrasonix Ergosonix 500 is intended for use in obstetrics/gynecology, general radiology examinations by a qualified physician, to aid in the diagnosis and evaluation of soft tissues, by generating 2 dimensional images, time motion images and biometric studies. The specific intended uses of this system include: abdominal, small parts, peripheral vascular, musculo-skeletal (conventional), musculo-skeletal (superficial), cephalic, small organ (breast, thyroid, testicle), trans-vaginal, trans-rectal, pediatric and fetal imaging, cardiac (adult) and cardiac (pediatric).

5.0 Comparison to Predicate Device

The Ultrasonix Ergosonix 500 diagnostic ultrasound scanner is substantially equivalent to the predicate devices with respect to intended use / indications for use, principles of operation and technological characteristics.

6.0 Technological Characteristics

The technological characteristics are substantially similar to that of the predicates. The device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D or M-mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, PW Doppler, Color Flow Mapping Doppler, Power Doppler) are the same as a the predicate devices identified in item 2.5. Transducer patient contact materials are biocompatible.

The beam forming architecture is very similar to that of the predicate devices. The receiving and processing hardware is similar but more innovative in that it is a programmable system made of 2 building blocks, which can be reconfigured to operate the system in any imaging mode.

The parameters used to adjust image quality are the same as that seen in the predicates. This includes the use of TGC gain sliders, depth control, base control and angling, among others.

7.0 Safety Considerations

As a track 3 ultrasound device, the Ultrasonix Ergosonix 500 Ultrasound Diagnostic Scanner is designed to comply with the 'Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment (1992)" published by the National Electrical Manufacturers Association as UD –3.

With respect to limits on acoustic outputs, the Ultrasonix Ergosonix 500 Ultrasound diagnostic scanner complies with the guideline limits set in the *September 30, 1997*, Revision of 510(k) Diagnostic Ultrasound Guidance.

With regard to general safety, the Ultrasonix Ergosonix 500 Ultrasound diagnostic scanner is designed to comply with IEC 601-1(1988) Medical Electrical Equipment, Part 1: General Requirements for Safety, and IEC 60601 – 2-37: Particular Requirements For The Safety Of Ultrasonic Medical Diagnostic And Monitoring Equipment.

The device's acoustic output limits are:

I_{SPTA} (d)	720mW/cm^2
TIS/TIB/TIC	0.1 – 4.0 (Range)
Mechanical Index (MI)	1.9 (Maximum)
I_{SPPA} (d)	0-700 W/cm^2 (Range)

The limits are the same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2002

Mr. Ken Seto
Quality Assurance / Regulatory Engineer
Ultrasonix Medical Corp.
Jack Bell Research Centre
535 – 2660 Oak St.
VANCOUVER BC
CANADA V6H 3Z6

Re: K020630
Trade Name: Ultrasonix Ergosonix 500 Ultrasound Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYN and IYO
Dated: May 3, 2002
Received: May 10, 2002

Dear Mr. Seto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasonix Ergosonix 500 Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number

4C1 Transducer
L7 Transducer
EC6.5 / 128 Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

The Ergosonix 500 System

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify) *1	Other (specify) *2
Ophthalmic										
Fetal		✓	✓	✓		✓	✓	✓	✓	✓
Abdominal		✓	✓	✓		✓	✓	✓	✓	✓
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		✓	✓	✓		✓	✓	✓	✓	✓
Small Organ (specify)		✓	✓	✓		✓	✓	✓	✓	✓
Neonatal Cephalic		✓	✓	✓		✓	✓	✓	✓	✓
Adult Cephalic		✓	✓	✓		✓	✓	✓	✓	✓
Cardiac										
Transesophageal										
Transrectal		✓	✓	✓		✓	✓	✓	✓	✓
Transvaginal		✓	✓	✓		✓	✓	✓	✓	✓
Transurethral										
Intravascular										
Peripheral Vascular		✓	✓	✓		✓	✓	✓	✓	✓
Laparoscopic										
Musculo-skeletal Conventional		✓	✓	✓		✓	✓	✓	✓	✓
Musculo-skeletal Superficial		✓	✓	✓		✓	✓	✓	✓	✓
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Small parts: thyroid, breast, testicles, etc...

*1: B&M, B&PWD, B&CD&PWD, B&CD, B&AD, B&AD&PWD

*2: Compound Imaging (BX), Tissue harmonic imaging

Tissue Harmonic is an option in B mode, not an actual scanning mode.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020630

Ergosonix 500 and 4C1 Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify) *1	Other (specify) *2
Ophthalmic										
Fetal		✓	✓	✓		✓	✓	✓	✓	✓
Abdominal		✓	✓	✓						
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		✓	✓	✓		✓	✓	✓	✓	✓
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

*1: B&M, B&PWD, B&CD&PWD, B&CD, B&AD, B&AD&PWD

*2: Compound Imaging (BX), Tissue harmonic imaging

Tissue Harmonic imaging is an option in B mode, not an actual scanning mode.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020630

Ergosonix 500 and L7 Transducer

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify) *1	Other (specify) *2
Ophthalmic										
Fetal		✓	✓	✓		✓	✓	✓	✓	✓
Abdominal		✓	✓	✓		✓	✓	✓	✓	✓
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		✓	✓	✓		✓	✓	✓	✓	✓
Small Organ (specify)		✓	✓	✓		✓	✓	✓	✓	✓
Neonatal Cephalic		✓	✓	✓		✓	✓	✓	✓	✓
Adult Cephalic		✓	✓	✓		✓	✓	✓	✓	✓
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		✓	✓	✓		✓	✓	✓	✓	✓
Laparoscopic										
Musculo-skeletal Conventional		✓	✓	✓		✓	✓	✓	✓	✓
Musculo-skeletal Superficial		✓	✓	✓		✓	✓	✓	✓	✓
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Small parts: thyroid, breast, testicles, etc...

*1: B&M, B&PWD, B&CD&PWD, B&CD, B&AD, B&AD&PWD

*2: Compound Imaging (BX), Tissue harmonic imaging

Tissue Harmonic Imaging is an option in B mode, not an actual scanning mode.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seguran

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020630

Ergosonix 500 and EC6.5 / 128 Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify) *1	Other (specify) *2
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		✓	✓	✓		✓	✓	✓	✓	✓
Transvaginal		✓	✓	✓		✓	✓	✓	✓	✓
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

*1: B&M, B&PWD, B&CD&PWD, B&CD, B&AD, B&AD&PWD

*2: Compound Imaging (BX), Tissue harmonic imaging

Tissue Harmonic is an option in B mode, not an actual scanning mode.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020630